REMARKS

PRIORITY/DECLARATION

The serial number of the predecessor application has been corrected on Pages 1 and 18 of the specification. As far as the objection to the specification, the inventors are no longer at the company. Applicant is taking steps to locate them and execute a declaration should one be deemed necessary.

REJECTIONS UNDER SECTION 112, SECOND PARAGRAPH

Claims 18 and 19 have been amended in accordance with the examiner's suggestions. It is urged that these amendments overcome the rejections and place the application in condition for allowance. The amendments do not change the scope of the claim in any way or form, but simply clarify what was already claimed.

The objection to claims 2-13 and 15-16 is not understood. It was requested that the dependent claims be introduced with the article "The," but no explanation was given as to why such a change is necessary. Clarification is therefore requested.

REJECTION UNDER SECTION 103

In previous responses, Applicant had provided evidence that it would not have been obvious to use gp120 as a measure of latent viral load. That argument was not based on "unexpected results" (although Applicant reserves the right to provide such evidence in the future), as alleged in the Office Action, but was based on the fact that the skilled worker would have been uncertain whether gp120 could be used as a measure of latent viral load. Evidence of this fact was provided by Fessel et al. who studied HIV-infected patients who had high levels of circulating viral RNA – an indication of HIV-infection – but also high levels of CD4+ cells, a phenotype not expected in patients with such clinical blood chemistry. By analyzing the blood of these patients, they found that the circulating viral RNA apparently did not encode high numbers of infectious viral particles. *See*, e.g., Page 2 of Response filed March 19, 2001. This evidence was rejected by the examiner, apparently, because its date of publication was allegedly after the filing date of the present application.

In fact, Fessel's findings were simply an explanation of facts already in the published literature. For example, Fessel et al. refers to the "paradoxic response to HAART in that their CD4+

PBMC levels increase substantially but their levels of plasma HIV RNA remain high (6-11)." Fessel et al., Page 314, Column 2. (Four of the six cited references were published in 1998, prior to the publication date of the present application.) In other words, based on the type of literature cited in the Office Action, the skilled worker might have been led to believe that serum concentrations of HIV RNA were a reliable indicator of the progression of HIV infection. In reality, the literature as a whole, including the references cited by Fessel et al., show that in many cases there was no correlation between high levels of serum HIV RNA and the severity of the disease. Thus, until a particular biochemical marker associated with HIV infection (i.e., viral RNA, CD4+, p24, gp120 etc.) was analyzed, it could not have predicted whether such marker could be used to determine latent viral load. Accordingly, there would have been no motivation with an expectation of success to modify the prior art to arrive at the present invention.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please replace the paragraph on page 1, lines 4-8 with the following amended paragraph.

This application is [a continuation-in-part of 09/139,633] related to 09/139,663 filed August 25, 1998 which is a 371 of PCT/US97/18649, filed October 15, 1997, which is a continuation-in-part of U.S. Ser. No. 08/732,782, filed October 15, 1996, now U.S. Pat. No. 5,817,458, and U.S. Ser. No. 08/732,784, filed October 15, 1996, now U.S. Pat. No. 5,714,390, all of which are incorporated by reference herein.

Please replace the paragraph on page 18, lines 3-10 with the following amended paragraph.

Without further elaboration, it is believed that one skilled in the art can, using the preceding description, utilize the present invention to its fullest extent. The preceding preferred specific embodiments are, therefore, to be construed as merely illustrative, and not limiting of the remainder of the disclosure in any way whatsoever. The entire disclosure of all applications, patents and publications, cited above and in the figures are hereby incorporated by reference in their entirety, including, U.S.S.N [09/139,633] 09/139,663 filed August 25, 1998; PCT/US97/18649, filed October 15, 1997; U.S. Pat. No. 5,817,458; and U.S. Pat. No. 5,714,390.

IN THE CLAIMS:

Please amend the claims as follow:

18. (Amended) A method of determining latent viral load in a host infected with HIV comprising,

depleting a cell population [of] comprising intact cells susceptible to HIV-infection expressing cell-surface gp120, and

determining, in said depleted cell population, the number of intact cells expressing cell-surface gp120, wherein said depleted cell population has been contacted [under effective conditions] with an agent [effective for] capable of activating HIV integrated into the genome of said cells under conditions effective for said agent to activate integrated HIV,

whereby said latent viral load is the determined number of cells.

19. (Amended) A method of determining latent viral load in a host infected with HIV comprising,

depleting a cell population [of] comprising intact cells susceptible to HIV-infection expressing cell-surface gp120,

contacting said depleted cell population[, under effective conditions,] with an agent [effective for] capable of activating HIV integrated into the genome of said cells under conditions effective for said agent to activate integrated HIV, and

determining, in said depleted cell population, the number of intact cells expressing cell-surface gp120,

whereby said latent viral load is the determined number of cells.